

2010 No. 404

MEDICINES

The Medicines (Pharmacies) (Applications for Registration and Fees) Regulations (Northern Ireland) 2010

Made - - - - - *3rd December 2010*

Coming into operation - - - - - *1st January 2011*

The Minister for Health, Social Services and Public Safety^(a) makes the following Regulations in exercise of the powers conferred by sections 75(1) and (2), 76(1), (2), and (4), 129(5) and 134(3) of, and paragraphs 6 and 8 of Schedule 4 to, the Medicines Act 1968^(b).

In accordance with section 129(6) of that Act, the Minister has consulted such organisations as appear to him to be representative of interests likely to be substantially affected by these Regulations.

In accordance with paragraph 6 of Schedule 4 to that Act it is the opinion of the Minister that there are special circumstances which render it expedient to make these Regulations.

Citation and commencement

1. These Regulations may be cited as the Medicines (Pharmacies) (Applications for Registration and Fees) Regulations (Northern Ireland) 2010 and shall come into operation on 1st January 2011

Interpretation

2.—(1) In these Regulations —

“the Act” means the Medicines Act 1968;

“emergency” means an emergency of the type described in section 19(1)(a) of the Civil Contingencies Act 2004^(c) (meaning of “emergency”) read with subsection 2(a) and (b) of that section.

(2) The Interpretation Act (Northern Ireland) 1954^(d) shall apply to these Regulations as it applies to an Act of the Assembly.

(a) See s.95 (5) of, and paragraph 10 of Schedule 12 to, the Northern Ireland Act 1998 (c.47). The Department for which the Minister is responsible was renamed by S.I 1999/283 (N.I.1) Article 3(6).

(b) 1968 c.67. Section 75 was amended by S.I 1968/1699. Sections 75 and 76 were recently amended by S.I 2010/231, see Article 68, and Schedule 4 Part 1, paragraphs 1(9) and (10). The word “prescribed” is defined in section 132(1) of the 1968 Act.

(c) 2004 c.36

(d) 1954 c.33 (N.I)

Applications for registration

3.—(1) Every application for the registration of premises under section 75 of the Act shall be made in writing and shall be given or sent to the registrar.

(2) Every such application shall be made and signed by or on behalf of the person carrying on, or who intends to carry on, a retail pharmacy business in the premises to which the application for registration relates.

(3) Every such application shall contain or be accompanied by the particulars specified in the Schedule.

(4) A separate application for registration shall be made in respect of each of the premises to be registered.

Temporary Registration with regard to emergencies involving loss of human life or illnesses etc

4.—(1) In the circumstances set out in paragraph (2), the registrar may—

- (a) accept an application under section 75 of the Act in respect of premises which is not accompanied by all of the particulars specified in the Schedule (but may insist on some of those particulars being provided); and
- (b) determine that the fee otherwise payable in respect of registration of premises under regulation 3(1) is to be waived in whole or in part.

(2) Those circumstances are—

- (a) that the Minister has advised the register that an emergency has occurred, is occurring or is about to occur;
- (b) an application under section 75 is made to the registrar; and
- (c) for the purposes of mitigating the effects of that emergency, a person carrying on a retail pharmacy business at premises entered in the register has agreed to enter into arrangements with the Regional Health and Social Care Board (a), in order to provide pharmaceutical services at other premises which are not registered (“the temporary premises”);

(3) Registration of the temporary premises shall cease to have effect if the Minister advises the registrar that the circumstances that led the Minister to advise the registrar as mentioned in paragraph (2)(a) no longer exist.

Fees

5.—(1) The fees payable for the purposes of section 75 of the Act in respect of the registration of any premises shall be £113.

(2) The retention fee payable under section 76(1) of the Act shall be £155.

(3) The additional sum by way of penalty for the purposes of section 76(2) of the Act shall be £317.

Demand for retention fee

6. The demand under section 76(2) of the Act for the payment of a retention fee shall be made in writing and shall be sent by the registrar by registered post or recorded delivery.

(a) Established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009 (2009 c.1 (N.I))

(L.S.)

Michael McGimpsey
Minister for Health, Social Services and Public Safety

SCHEDULE

Regulation 3(3)

Particulars required in an application for registration of premises

1.—(1) Name of the person carrying on, or intending to carry on, a retail pharmacy business and his private residential address.

(2) In the case of a partnership carrying on, or intending to carry on, a retail pharmacy business the names and private residential addresses of all the partners.

(3) In the case of a body corporate carrying on, or intending to carry on, a retail pharmacy business the registered name and the address of the registered office of the body.

(4) In the case where a retail pharmacy business is being carried on by a representative of a pharmacist (as defined by section 72 of the Act) and the business is under the personal control of a pharmacist (in accordance with section 72(2) of the Act) the latter pharmacist's name and the number of his certificate of registration.

2. Where a person or, as the case may be, a partnership or body corporate is carrying on or intends to carry on a retail pharmacy business under a business name which does not correspond to the name of the person or, as the case may be, the names of the partners or the name of the corporate body, the business name under which such business is being, or is to be, carried on.

3. Name of the pharmacist or if more than one the names of all the pharmacists under whose personal control the retail pharmacy business is or is to be carried on at all the premises to which the application relates and in the case of a body corporate the name of the superintendent under whose management the retail pharmacy business is or is to be carried on and the number of the certificate of registration of each pharmacist and, as the case may be, superintendent.

4. The full postal address of the premises to which the application relates.

5. Where the application for registration relates to premises in respect of which there has been a change of ownership of the retail pharmacy business:—

- (a) name and address of the immediate former owner of that business and the date of such change of ownership;
- (b) the date or intended date of the commencement of such business;
- (c) a brief description of the premises including the internal layout of the premises as respects the areas where medicinal products are or are intended to be sold, supplied, prepared, dispensed or stored together with—
 - (i) a statement showing whether or not there are arrangements so as to enable supervision to be exercised by a pharmacist of any dispensing and sale of medicinal products at one and the same time; and
 - (ii) a sketch plan, drawn to scale, showing the areas and the layouts to which this paragraph relates.

EXPLANATORY NOTE

(This note is not part of the Regulations)

The Medicines (Applications for Registration and Fees) Regulations (Northern Ireland) 2010, “these Regulations,” are being made under sections 75(1) and (2), 76(1),(2) and (4), 129(5) and 134(3) of, and paragraphs 6 and 8 of Schedule 4 to the Medicines Act 1968, “the Act” to replace the Medicines (Applications for Registration and Fees) Regulations 1973, which were revoked by the Pharmacy Order 2010 (S.I.2010/231).

These Regulations prescribe the manner of making, and the particulars to be contained in, applications for registration under Section 75 of the Act at premises at which a retail pharmacy business is or is to be carried on (Regulation 3), the fees to be paid on the application for such registration, the subsequent annual fees (referred to in the Act as “retention fee”) and the amount of the penalty for failure to pay the retention fee within the time laid down in the Act (Regulation 6).

Regulation 4 allows the registrar to accept applications from existing pharmacy businesses for registration of additional pharmacy premises during an emergency without the need to supply all the information usually required to accompany such applications and to waive all or part of the registration fee. Regulation 6 prescribes the manner in which the demand for the payment of the retention fee is to be made.

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